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COURT OF APPEAL, FOURTH APPELLATE DISTRICT

DIVISION ONE

STATE OF CALIFORNIA

IN RE COORDINATED LATEX GLOVE LITIGATION.	D036680 (Consolidated with D037435) JCCP No. 4003-014 (Alameda Super. Ct. No. 77125-2)

APPEAL from a judgment and order of the Superior Court of San Diego County, William C. Pate, Judge. Affirmed.

Bien & Summers, E. Elizabeth Summers; Kazan, McClain, Edises, Simon & Abrams, Philip A. Harley, Wes Wagnon and James L. Oberman, for Plaintiff and Appellant.

Crosby, Heafey, Roach & May, James C. Martin, Thomas M. Freeman, Denise M. Howell; Seyfarth, Shaw, Robert M. Mitchell and Lawrence E. Butler, for Defendants and Respondents.

In this opinion we discuss the two-pronged test for a strict liability manufacturing defect as applied to the production of latex gloves. (*Barker v. Lull Engineering Co.*

(1978) 20 Cal.3d 413, 432 (*Barker*).) This products liability action filed by plaintiff Christine McGinnis was the first to go to trial in a group of cases in coordinated proceedings involving allegations against various defendants who manufactured or distributed latex gloves, used by the plaintiffs at their work, that contained natural or artificial substances that were alleged to be causative factors in the development of the plaintiffs' serious latex allergies. McGinnis's individual action against Baxter Healthcare Corporation (Baxter) went to jury trial on her manufacturing defect strict liability theory, as well as negligence and failure to warn. A defense verdict was obtained on failure to warn and negligence, but the jury found a manufacturing defect had been proven and awarded McGinnis compensatory damages.

However, in posttrial proceedings, Baxter moved for judgment notwithstanding the verdict (JNOV) and for new trial on the manufacturing defect issue, and both motions were granted by the trial court. (Code of Civ. Proc., §§ 629, 657.) McGinnis appeals the ensuing judgment, arguing the trial court applied an incorrect legal standard in ruling on the motions, such that under a proper analysis, there was substantial evidence that Baxter's latex gloves were defective, either as a defective product that differed from the manufacturer's intended result or that differed "from other ostensibly identical units of the same product line." (*Barker, supra*, 20 Cal.3d at p. 429.)

McGinnis also makes a last ditch claim that the court erred in refusing to instruct the jury on her design defect theory, based on a consumer expectations approach. (See *Morson v. Superior Court* (2001) 90 Cal.App.4th 775, 784 (*Morson*), a prior mandamus proceeding in these consolidated cases, originating in this McGinnis case, in which this

court rejected the application of that same consumer expectations theory to latex gloves in the health care context.)

Our examination of the record and the applicable legal principles persuades us that the trial court correctly granted JNOV under the two-part test for a manufacturing defect and that no new trial on that theory is warranted in light of that determination. Nor was there any reversible instructional error regarding design defect. We need not reach the alternative grounds on which the trial court denied Baxter's new trial motion (lack of causation evidence and inconsistent verdicts). We affirm the judgment in favor of Baxter.

FACTUAL AND PROCEDURAL BACKGROUND

A

Pleadings and Background

On review of this order granting JNOV, we state the facts in the light most favorable to the jury's verdict. (*Hansen v. Sunnyside Products, Inc.* (1997) 55 Cal.App.4th 1497, 1510.) As this court outlined the background facts in *Morson*, *supra*, 90 Cal.App.4th 775, the plaintiffs in these coordinated cases pursue a theory of product liability that the latex gloves supplied to them caused a serious, disabling, and potentially life-threatening allergy to all forms of natural rubber latex (referred to as NRL) to develop, even though they did not have this condition prior to their extensive use of latex gloves. They accordingly claim improperly designed and manufactured NRL gloves caused this allergy by allowing excessive levels of allergenic agents, latex proteins, to remain present on the surface of the gloves during manufacture. It is not disputed that

such agents may be greatly reduced or eliminated through washing and chlorinating procedures in the design and manufacture of these gloves. The issue is whether, as plaintiff complains here in the context of her manufacturing defect claim, Baxter "took too long" to make that its standard practice, in light of its knowledge and research.

McGinnis (sometimes referred to as Plaintiff) was employed as a respiratory technician by various hospitals and care facilities for a number of years between 1982 and 1996, and used thousands of pairs of Baxter NRL gloves during her career. The brands she used over 93 percent of the time, Flexam powdered exam gloves and Triflex powdered surgical gloves, were manufactured at Baxter plants in the United States and Malaysia. In addition, Baxter purchased gloves from other manufacturers to sell under its brand names ("buy-in gloves"). Baxter began to receive reports around 1988-1989 that some health care workers commonly exposed to NRL products were developing severe latex allergies. It began a research and development effort in its glove production and purchases around that time, as we later describe.

Both through her own use of NRL products and the use of others around her, McGinnis became sensitized to that substance to the point of developing a serious Type I latex allergy, which caused her in 1995 to experience symptoms going beyond mild symptoms of itching and skin irritation, to a life-threatening anaphylactic reaction (respiratory distress, hives and other symptoms). She was forced to leave health care work, has undergone emergency medical treatment for such reactions, and must carry medication to treat them at all times, as her allergy is a lifelong condition.

McGinnis sued Baxter and other defendants (who were no longer involved in the case by the time of trial and this appeal) on various products liability and negligence theories. The matter went to jury trial on strict liability theories of manufacturing defect and failure to warn of a defective product, and well as negligence through manufacture and failure to warn.

B

Jury Trial: Evidence

Extensive testimony and documentary evidence was presented at trial about the manufacturing process of NRL gloves. The critical qualities provided by rubber gloves to the health care profession include barrier protection and tactile sensitivity. The market for gloves grew tenfold from 1983 to 1990 after the FDA recommended and then in 1987 adopted universal precautions for health care workers to prevent the spread of AIDS and hepatitis, requiring expanded use of gloves and other barrier protection equipment. By 1990, Baxter was manufacturing and distributing approximately four billion gloves per year, which represented approximately half of the American medical glove market. Most of these gloves were made of NRL.

The multistep manufacturing process begins with the tapping of rubber trees and centrifuging and mixing of raw rubber, the preparation of glove molds to be positioned on a continuous conveyor line, the dipping of the mold in coagulant and rubber compounds, the leaching in water of the molds, curing, rinsing, powdering, chlorination and sterilization, and packaging of the gloves. (*Morson, supra*, 90 Cal.App.4th at pp. 780-781.) Plaintiff presented evidence that additional washing and chlorination of the

gloves would reduce allergenic protein levels, while Baxter presented evidence that these steps might lead to defects in barrier protection such as pinholes, tearing, or a change in texture. (*Id*. at p. 782.) Baxter continued its defense: "Additionally, each of these steps may differ from line to line, glove to glove, and plant to plant depending on line speed, temperature, plant configuration and other conditions." (*Id*. at p. 781.) Accordingly, "[e]ach of the steps must be performed with an acute awareness of barrier protection issues, with an eye toward ensuring that the function of this life-saving medical device will not be compromised." (*Id*. at p. 782.)

Baxter's witnesses testified about the company's efforts to reduce the protein levels in their products, in response to consumer complaints received as part of the process of federal regulatory monitoring of the production of gloves. From 1989 through 1991, Baxter sold over 15 billion gloves, and received a total of 10 user complaints describing Type I severe allergic reactions to NRL gloves. Dr. Wava Truscott, Baxter's manager of laboratories for the applicable division, was assigned to head the investigation of the glove protein allergy problem, beginning in 1988. The task included assessing many different production lines and dealing with many different aspects of production, and it appears that Truscott's efforts were at first an uphill battle. She was concerned that during these years, Baxter was perceived as dragging its corporate feet on the matter. By 1991, her research had proposed a target or threshold level of protein for gloves, and she worked with product engineer Charles Gosnell to test her research. Complaints had been received about both high and low protein level gloves.

In response to the problem, by 1992, Baxter had implemented protein reduction techniques on all its production lines. By 1994, Baxter was requiring all its gloves to undergo a post-cure rinse to reduce surface protein levels. Later, a post-cure protein leach procedure was added. Baxter also made educational efforts about NRL allergies for health care workers, presenting traveling seminars as part of its marketing efforts. Around 1992-1994, it was advertising its gloves as "The Right Choice," due to Baxter's research and improvements in its manufacturing processes regarding allergens.

Plaintiff presented evidence from a manufacturing expert, Dr. Broutman, about the methods for and the feasibility of reducing protein levels, and his opinion that Baxter did not make desirable changes as quickly as possible. Extensive protein level evidence was offered by Plaintiff of Baxter's research and manufacturing changes for different glove types at different production facilities. For example, documents were introduced about tests run at different Baxter plants in the early 1990's, its internal memoranda among scientific and manufacturing staff to propose methods to reduce protein levels, including data on different gloves tested, and its dealings with the makers of its "buy-in" gloves on the subject.

With respect to the "buy-in" line of gloves that Baxter bought from others and distributed, mainly after 1992, Baxter was not requiring the other manufacturers to use the techniques it was developing to reduce protein levels in the gloves during the time that McGinnis was using them. The buy-in gloves were labeled the same as Baxter-produced gloves, so that a user could not tell whether a particular pair was manufactured

by Baxter or another company. Beginning in 1994, Baxter tested every lot of these gloves for protein levels.

Another line of evidence presented had to do with the sufficiency of the warnings provided by Baxter on its products regarding potential allergic reactions to NRL. Baxter began to label its latex gloves for latex content in 1992. In March 1993, the FDA announced its plans to issue regulations requiring manufacturers to state the latex content of medical devices such as gloves. Although the FDA was conducting research in the area of latex allergies, it did not require warning labels on that subject until 1996. Until 1998, due to concerns about the success of the AIDS etc. universal precautions requirement of glove usage, the FDA prohibited glove manufacturers from making comparisons about protein levels of their product. Also until 1998, there were no FDA protein level requirements or standards, such as had been established for strength and barrier protection qualities of the gloves. Specifically, these 1998 FDA protein level requirements or standards were implemented only for a low protein line of gloves.

Further, extensive testimony from various health care professionals was presented regarding the genesis of allergic conditions in the human body, specifically with reference to NRL allergies. (*Morson, supra,* 90 Cal.App.4th at p. 782.) McGinnis presented testimony about her health condition and her claimed damages.

C

Jury Trial: Instructions and Argument

At the outset of trial, the jury was preinstructed on the elements of claims for both manufacturing defects and design defects. However, by the conclusion of the evidence, McGinnis's claims no longer included a strict liability design defect cause of action, due in part to the ruling that we reviewed in the prior mandamus proceeding, *Morson*, *supra*, 90 Cal.App.4th at page 784, that precluded her from presenting a design defect theory based on consumer expectations. McGinnis did not present any alternative design defect theory under a risk-benefit analysis. (*Id.* at p. 785.) In accordance with that ruling, the trial court declined to instruct the jury on the consumer expectation test for a design defect. McGinnis contends this amounted to a nonsuit on design defect, while Baxter argues she simply did not pursue this claim further.

Thus, at trial, McGinnis went to the jury on her manufacturing defect claim, failure to warn of a defect and/or through negligence, and negligent manufacture and/or design. She stated during the in limine motion hearings that it was never her theory that the gloves were defective simply because they were made of latex as opposed to some other material, but rather that there were manufacturing defect problems, as well as failure to warn problems.

On the manufacturing defect claim, the jury was instructed in the language of BAJI No. 9.00.3 as follows:

> "The essential elements of a claim based upon an alleged manufacturing defect are:

> "1. The defendant, Baxter Healthcare Corporation, was the manufacturer and supplier of a product, namely natural rubber latex gloves. [¶] 2. The product possessed a defect in its manufacture. [¶] 3. The defect in manufacture existed when the product left the defendant's possession. [¶] 4. The defect in manufacture was a cause of injury to the plaintiff, and [¶] Plaintiff's injury resulted from the use of the product that was reasonably foreseeable to the defendant. [¶] A defect in the manufacture of a product exists if the product differs from the manufacturer's intended result, or if the product differs from apparently identical products from the same manufacturer."

The jury also received instructions about the failure to warn and negligence theories.

Plaintiff's counsel presented closing argument that focused upon the instruction about the manufacturing defect claim, BAJI No. 9.00.3: "A defect exists if the product differs from the intended result." He argued that the Baxter witnesses testified they had the intent, starting in 1990, to produce a low protein glove, but that although "their intentions were good, their execution was bad. And that creates a defect. They didn't execute their intent." Also, Plaintiff's counsel argued that the product could also be defective under the test "if the product differs from apparently identical products from the same manufacturer." He compared the gloves manufactured in Malaysia by Baxter, the buy-in gloves, and the United States-made gloves, and argued that these apparently similar products were actually different, so the test was satisfied.

In contrast, Baxter argued that the protein level evidence offered by Plaintiff had not been placed in context with any applicable government requirements, and that at the time Dr. Truscott was investigating the problem, complaints had been received about both high protein and low protein gloves, which made analysis at that point inconclusive.

Before and after 1992, Baxter was constantly tinkering with the system to get the best protein testing system in place. This protein testing system had to be implemented while keeping production up, due to the health care profession's need for universal precautions equipment. Baxter's position was that its personnel were at the top of the heap in the production field, and although they were not perfect, they acted reasonably.

D

Jury Verdict

The jury returned a verdict finding that a manufacturing defect had been proven and awarded McGinnis net compensatory damages of $886,921.20. The jury also found Baxter had been negligent but there had been no causation of her injuries through negligence. A comparative fault finding was made assessing 70 percent of the negligence to Baxter, 15 percent to McGinnis, and 15 percent to her previous hospital employer (not a party to the action). The jury also rejected McGinnis's claim that a warning defect was present.

E

Baxter's Motions for JNOV and New Trial

Following trial, Baxter filed its motions for JNOV and new trial. It argued that with respect to the manufacturing defect finding, no substantial evidence supported the verdict. It also argued the causation findings were inconsistent and lacked support in the evidence, and excessive damages had been awarded.

After briefing and argument, the trial court granted the Baxter motion for JNOV on the single cause of action on which McGinnis had prevailed, manufacturing defect

under a strict products liability theory. The court noted that no cause of action for design defect was submitted to the jury. The court found that the jury's verdict on manufacturing defect was not supported by the evidence, stating its reasoning as follows:

> "A manufacturing defect occurs when a product deviated from its intended design. Plaintiff had the burden of demonstrating there was a flaw in the manufacturing process whereby the injury-inflicting product or products deviated from the manufacturer's design or specification and thus was manufactured differently from the prototype. [¶] No evidence was introduced at trial that any of the gloves involved in the contributing to Plaintiff's injuries, in any manner deviated from the design for said gloves. Plaintiff's evidence tended to show that the gloves were defective in their design, since the design did not require the elimination or substantial reduction of protein that collected on the glove surface during its manufacture. [¶] The issue of design defect was not submitted to the jury for its determination, although a substantial portion of the evidence adduced at trial related to that issue."

In the alternative, the trial court granted the motion for new trial on the same grounds, with respect to the manufacturing defect theory. Although the order does not reflect the details of the new trial ruling, the transcript of the hearing shows that the trial court denied the new trial motion insofar as it argued insufficient evidence of causation and/or inconsistent special verdicts on causation. The excessive damages claim was also rejected.

McGinnis appealed the posttrial orders and the judgment, and her appeals were consolidated.

DISCUSSION

McGinnis's appeal raises the same basic concerns about the trial court's order with respect to both the Baxter motion for JNOV and its motion for new trial. She argues the

trial court incorrectly applied both the alternative tests for a manufacturing defect as set forth in *Barker, supra,* 20 Cal.3d 413. There, the Supreme Court opined (optimistically, in hindsight) that defining the concept of a product defect "raises considerably more difficulties in the design defect context than it does in the manufacturing or production defect context. [¶] In general, a manufacturing or production defect is readily identifiable because *a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line*." (*Id.* at p. 429.) These concepts form the basis of BAJI 9.00.3, defining a manufacturing defect, which was given to the jury here.[1]

McGinnis's initial criticism is that the trial court mistakenly evaluated the evidentiary record only in light of the "intended result test," by first requiring evidence that the high protein gloves that McGinnis used departed from Baxter's formal product design, prototype, or specifications, and secondly, by finding there was no such evidence. McGinnis next argues that the trial court failed to recognize that the alternative formulation of the test applied and was satisfied here, because there is substantial

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1 BAJI 9.00.3 reads as follows: "The essential elements of a claim based upon an alleged manufacturing defect are: [¶] 1. The defendant [_____] was the (manufacturer, supplier, etc.) of a product, namely (identify the product); [¶] 2. The product possessed a defect in its manufacture; [¶] 3. The defect in manufacture existed when the product left the defendant's possession; [¶] 4. The defect in manufacture was a cause of injury to the plaintiff; and [¶] 5. Plaintiff's injury resulted from a use of the product that was reasonably foreseeable to the defendant[s]. [¶] A defect in the manufacture of a product exists if the product differs from the manufacturer's intended result or if the product differs from apparently identical products from the same manufacturer."

evidence that the high protein gloves she used differed from "apparently identical" gloves that Baxter also produced or distributed, due to the different sources from which Baxter obtained its gloves and its varying production techniques over time. We will discuss these arguments in terms of the two procedural contexts in which the order was made, with attention to the separate standards for each ruling.

I

JUDGMENT NOTWITHSTANDING THE VERDICT

The standards to apply in reviewing a ruling on a motion for JNOV are well established. "'The trial court's discretion in granting a motion for judgment notwithstanding the verdict is severely limited.' [Citation.] ""The trial judge's power to grant a judgment notwithstanding the verdict is identical to his power to grant a directed verdict [citations]. The trial judge cannot reweigh the evidence [citation], or judge the credibility of witnesses. [Citation.] If the evidence is conflicting or if several reasonable inferences may be drawn, the motion for judgment notwithstanding the verdict should be denied. [Citations.] 'A motion for judgment notwithstanding the verdict of a jury may properly be granted only if it appears from the evidence, viewed in the light most favorable to the party securing the verdict, that there is no substantial evidence to support the verdict. If there is any substantial evidence, or reasonable inferences to be drawn therefrom, in support of the verdict, the motion should be denied.' [Citation.]"' [Citation.] The trial court cannot consider witness credibility. [Citation.]" (*Hansen v. Sunnyside Products, Inc., supra*, 55 Cal.App.4th at p. 1510.)

When an appellate court reviews an order granting JNOV, it will "'resolve any conflict in the evidence and draw all reasonable inferences therefrom in favor of the jury's verdict. [Citation.]' [Citation.]" (*Hansen v. Sunnyside Products, Inc.*, *supra*, 55 Cal.App.4th at p. 1510.)

A

Comparison of Definitions of Product Defects: Manufacturing/Design

As explained by the Supreme Court in *Brown v. Superior Court* (1988) 44 Cal.3d 1049 (*Brown*), under *Barker's* strict products liability analysis, there are three types of product defects: "First, there may be a flaw in the manufacturing process, resulting in a product that differs from the manufacturer's intended result. The archetypal example of such a defect was involved in *Escola* [*v. Coca Cola Bottling Co. of Fresno* (1944)] 24 Cal.2d 453, a Coca Cola bottle that exploded. . . . [¶] Second, there are products which are 'perfectly' manufactured but are unsafe because of the absence of a safety device, i.e., a defect in design. This was the defect alleged in *Barker*. It held that a product is defectively designed if it failed to perform as safely as an ordinary consumer would expect when used as intended or reasonably foreseeable, or if, on balance, the risk of danger inherent in the challenged design outweighs the benefits of the design. [Citation.]" (*Brown, supra,* 44 Cal.3d at p. 1057.) The third type of defect "is a product that is dangerous because it lacks adequate warnings or instructions." (*Ibid.*)

As a further illustration of the development of the concept of a defect in the strict liability field, we may turn to *Jiminez v. Sears, Roebuck & Co.* (1971) 4 Cal.3d 379, 383, where the court reviewed prior case law to say that "a defective product is viewed as one

which fails to match the quality of most like products, and the manufacturer is then liable for injuries resulting from deviations from the norm: the lathe did not like other lathes have a proper fastening device, the brakes of the automobile went on unexpectedly, the drive shaft of a new car became disconnected."

Here, McGinnis's case relied on the first and third types of product defects listed in *Barker, supra,* 20 Cal.3d 413 and the jury rejected the third (failure to warn of a defect). Only the first type, manufacturing defect, is squarely presented as an issue in this appeal. (See pt. III, *post*, where we reject her effort to revive a direct design defect theory under a consumer expectations rubric, and where we note she did not effectively pursue the remaining design defect theory, risk-benefit.) Hence, our task is to see if, as McGinnis contends, substantial evidence was presented to support a manufacturing defect theory under either of the *Barker* formulations. We do this in tandem with evaluating the Baxter argument that McGinnis actually tried this case under a design defect approach, and her appellate argument on the manufacturing defect theory does not fit the facts like a glove.

In *Morson, supra,* 90 Cal.App.4th 775, this court relied on *Dierks v. Mitsubishi Motors Corp.* (1989) 208 Cal.App.3d 352, 354-355 as a statement of the difference between a defect in manufacture and a defect in design: "'The latter focuses upon whether the product was designed to perform as safely as an ordinary consumer would expect or whether the risk of danger inherent in the design outweighed the benefits of the design. [Citations.] The former focuses on whether the particular product involved in the accident was manufactured in conformity with the manufacturer's design. [Citations.]'" (*Morson, supra,* 90 Cal.App.4th at pp. 788-789.) There, we also cited to a treatise writer

for the concept that "'the line between design and manufacturing defects is not necessarily a sharp one. This is clear when one considers that the choice of quality control techniques may determine the rate of metallurgical flaws, which ordinarily would be characterized as "manufacturing defects" rather than design defects. One may note, moreover, that those kinds of entrepreneurial decisions are quite analogous to the sorts of choices that are made in selecting one product configuration or another on the basis of cost considerations.'" (*Id.* at p. 789, citing 1 Shapo, The Law of Products Liability (3d ed. 1994) ¶ 9.01(2), pp. 9-5 to 9-6.)

Also in *Morson, supra*, 90 Cal.App.4th 775, we noted that in general, the plaintiffs in these coordinated latex glove cases are alleging a theory of injury that "appears to have aspects common to both the design defect and manufacturing defect theories" (*id*. at p. 789), in that "the materials from which the latex gloves were made contained excessive amounts of latex rubber proteins close to the surface of the gloves, causing the Plaintiffs to become sensitized to them and to develop or to exacerbate an existing allergy." (*Ibid*.) We discussed the particular nature of this product as having primarily a protective or barrier function, leading to the choice of latex as an appropriate material, but also noting that the effect of this material and the manufacturing processes used "may well be to create in their users many degrees of allergic reactions. Understanding and assessing responsibility for such allergic reactions is a matter that is driven by the science of the manufacturing and preparation procedures, as well as the medical aspects of an individual's allergic reactions to various substances." (*Id.* at p. 793.)

From these observations, we are led to a further conclusion, that it is useless to focus on a distinction between a raw material of which a product is made (NRL), and the format or construction of the product itself (glove), for purposes of deciding if a strict liability defect is one of design or manufacture. Here, McGinnis stated during the hearings on the in limine motions that it was never her theory that the gloves were defective simply because they were made of latex as opposed to some other material, but rather she claimed there were manufacturing defect problems, as well as failure to warn problems. It is appropriate to view the product as a whole, composed of different components, including latex.

In other factual contexts, similar difficulties have arisen in analyzing the component parts of a whole product for purposes of applying the manufacturing defect test. In *Pierce v. Pacific Gas & Electric Co*. (1985) 166 Cal.App.3d 68, the appellate court concluded that a commercial supplier of electricity is subject to strict liability in tort for personal injuries caused by delivery of electricity at dangerously high voltage resulting from defects in a transformer. The facts were that due to a transformer malfunction, the defendant's utility's electricity arrived at the plaintiff's home at nearly 60 times its intended voltage, ultimately causing the plaintiff to suffer bodily injury. (*Id*. at p. 77.) However, the court noted that the utility defendant (PG&E) was not the manufacturer of the defective transformer, which some other electric company had made, such that the defendant PG&E, "never placed the transformer 'on the market' or in the stream of commerce. PG&E was, in essence, a consumer rather than a manufacturer of the transformer, and cannot be held strictly liable in tort for the transformer's defects per

se. [Citation.]" (*Id.* at p. 76.) However, the appellate court concluded that since the product, electricity, was delivered to the plaintiff's home by way of the defective transformer, and arrived at a harmful level of voltage and injured the plaintiff, it was error to grant a nonsuit in favor of the defendant utility, as a cause of action for strict liability in tort existed and personal injuries were shown. It did not make any difference that the utility could not be held strictly liable in tort for the transformer's defects "per se," as the subject product, electricity, harmed plaintiff anyway. (*Id.* at pp. 77, 84.) However, the court did not directly identify whether a manufacturing or design defect was shown, as to the electricity itself.

One explanation for this blending of theories was alluded to in *Artiglio v. Superior Court* (1994) 22 Cal.App.4th 1388, 1393 (*Artiglio*), in which this court noted "pre-*Brown* authorities lumped together the concepts of proper manufacture, lack of design defect and adequate warning." However, in *Artiglio* we further stated that in *Brown, supra,* 44 Cal.3d 1049, which rejected the theory of design defect for pharmaceuticals, the Supreme Court very clearly distinguished among the three concepts of fault, in the prescription drug context: "Liability for defective design could not be premised on strict liability, but would require proof of negligence. [Citation.] Strict liability would continue applicable for manufacturing defects; and liability for failure to warn of known or reasonably knowable risks in the use of the product remains viable 'under general principles of negligence.' [Citation.]" (*Artiglio, supra*, 22 Cal.App.4th at p. 1393.) *Artiglio* similarly concluded, based on the public policies identified in *Brown*, "that the entire category of

medical implants available only by resort to the services of a physician are immune from design defect strict liability." (*Artiglio, supra,* 22 Cal.App.4th at p. 1397.)

Of course, latex gloves, even as used in the health care field as this plaintiff did, are not prescription drugs, nor are they available "only by resort to the services of a physician," as in *Artiglio, supra,* 22 Cal.App.4th 1388 and *Brown, supra,* 44 Cal.3d 1049. Nor was this case pursued or instructed as a design defect case, as in *Artiglio* and *Brown*. Nevertheless, many of the same policy concerns apply, due to the closely related nature of these strict liability theories in this factual context, as we next explain.

B

Public Policy and Doctrinal Concerns

The Supreme Court's holding in *Brown, supra,* 44 Cal.3d 1049, was that "a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution." (*Id.* at p. 1069.) An important public policy considered by the court in reaching that decision was stated as follows: In the cases in which the subject product is used to make work easier or to provide pleasure (e.g., construction machinery, a lawnmower, or perfume) it is not unreasonable to impose strict liability for design defects. However, more protection for a manufacturer is justified where the product is created "to alleviate pain and suffering or to sustain life." (*Id.* at p. 1063.) Along these same lines, the court also referred to "other important medical products (wheelchairs, for example)," apparently to illustrate that harm to some users can be avoided for some medical

products, which would allow liability to be more freely imposed on a manufacturer. (*Id.* at p. 1063.) However, the court stated that "harm to some users from prescription drugs is unavoidable," and continued: "Because of these distinctions, the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use." (*Ibid*.) This led the court to reject a design defect theory of liability against a drug manufacturer for injuries caused by the defective design of a prescription drug, and also to reject an assertion "that a drug manufacturer should be held strictly liable for failure to warn of risks inherent in a drug even though it neither knew nor could have known by the application of scientific knowledge available at the time of distribution that the drug could produce the undesirable side effects suffered by the plaintiff." (*Id*. at p. 1065.)

Another important policy concern in the field of strict liability is that the doctrine "was never intended to make the manufacturer or distributor of a product its insurer. 'From its inception, . . . strict liability has never been, and is not now, absolute liability. . . . [U]nder strict liability the manufacturer does not thereby become the insurer of the safety of the product's user. [Citations.]' [Citation.]" (*Anderson v. Owens-Corning Fiberglas Corp.* (1991) 53 Cal.3d 987, 994.)

From these policy statements we are led to believe that the courts may take into account, in evaluating manufacturer liability for a product that seriously implicates concerns of alleviating pain and suffering or sustaining life, whether the product "was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution." (*Brown,*

supra, 44 Cal.3d at p. 1069.) In cases involving products that create significant scientific concerns with respect to research and innovation, more protection for a manufacturer is justified, than in cases of "other important medical products (wheelchairs, for example)," in which harm to some users can more readily be avoided, due apparently to their more mechanical nature. (*Id.* at p. 1063.) This has led to the rejection of design defect immunity for the more complex medical/pharmaceutical products.

Moreover, in reviewing this record for substantial evidence in support of a manufacturing or production defect theory, we must keep in mind the two formulations of the test: A defective product is one that "differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." (*Barker, supra,* 20 Cal.3d at p. 429.) Where do latex gloves fall along the continuum of strict liability theory, in light of public policy? We turn to the record to decide that question.

C

Application of Rules to this Evidentiary Showing

McGinnis first claims the trial court mistakenly evaluated the evidentiary record only in light of the "intended result test," by finding she failed to produce essential evidence that the high protein gloves that Baxter produced departed from its own design, specifications, or prototypes. She contends she showed, through the evidence of the research and data collection that Baxter was doing to reduce protein levels, that Baxter had internal standards that it was developing that constituted such evidence of "formal product design, prototype, or specifications."

McGinnis next argues the trial court failed to recognize that the alternative formulation of the *Barker* test applied, because substantial evidence was produced to show that the high protein gloves she used differed from "apparently identical" gloves that Baxter also produced or distributed, due to the different sources from which Baxter obtained its gloves and its evolving production techniques. The buy-in gloves were labeled the same as Baxter-produced gloves, but they were not subject to the same standards at the same times. Also, there were variances in protein levels among Baxter-produced gloves, depending on the lines that manufactured them.

On review of this order granting JNOV, we must ""resolve any conflict in the evidence and draw all reasonable inferences therefrom in favor of the jury's verdict. [Citation.]"' [Citation.]" (*Hansen v. Sunnyside Products, Inc., supra,* 55 Cal.App.4th at p. 1510.). Even when we do so, we have grave concerns that Plaintiff's evidence fails to make her case, when all the applicable policies are considered. For example, while Plaintiff presented evidence that additional washing and chlorination of the gloves would reduce allergenic protein levels, Baxter presented evidence that these steps might lead to defects in barrier protection such as pinholes, tearing, or a change in texture. (*Morson, supra,* 90 Cal.App.4th at p. 782.) Each line, glove, and plant was subject to variances due to line speed, temperature, plant configuration and other conditions. (*Id.* at p. 781.) Any changes were subject to the need to consider barrier protection issues, "with an eye toward ensuring that the function of this life-saving medical device will not be compromised." (*Id.* at p. 782.)

Other evidence in the record showed that while Baxter began to label its latex gloves for latex content in 1992, it was not required by the FDA to do so until after 1993. The FDA did not require warning labels in the area of latex allergies until 1996. Until 1998, due to concerns about the success of the universal precautions requirement of glove usage, the FDA prohibited glove manufacturers from making comparisons about protein levels of their product. Also until 1998, there were no FDA protein level requirements or standards, such as had already been established for strength and barrier protection qualities of the gloves. The 1998 FDA protein level requirements or standards were implemented only for a low protein line of gloves. Other glove types were not affected. None of this amounts to evidence that Baxter failed to meet externally imposed government product specifications.

Also, the evidence presented about Baxter's internal corporate protein reduction techniques, such as after 1992, requiring all its gloves to undergo a post-cure rinse and leach to reduce surface protein levels, raises the issue of whether these internal standards and practices can be used by Plaintiff to show earlier manufacturing techniques were defective. It is not disputed that Baxter personnel developed targets or goals for protein levels in the product. However, Plaintiff failed to show these were enforceable standards, departure from which would create a manufacturing defect. Plaintiff's approach would essentially penalize the manufacturer for doing documented research to respond to product complaints or to improve the product. This would contravene the public policies outlined in *Brown, supra,* 44 Cal.3d 1049, with respect to the use of these products by health care workers whose employers' goals are geared toward alleviating pain and

suffering, and also toward compliance with the requirements for universal precautions equipment, for protection of those workers and patients.

As stated in Baxter's respondent's briefs, it was uncontested at trial "that Baxter intended to, and did, produce and sell gloves with a wide range of protein levels." These gloves met Baxter's design specifications as they existed at all the relevant times. There was no set standard for protein levels under either Baxter's corporate policies or the government regulations. Plaintiff cannot convert these undisputed facts into an adequate showing of a manufacturing defect under the *Barker* tests.

We also evaluate the evidence in light of the Baxter argument that McGinnis actually tried this case under a design defect approach, and did not change her arguments into a manufacturing defect format until she realized the design defect approach was fatally flawed. Both the traditional definitions of manufacturing defect presuppose that a suitable design is in place, but that the manufacturing process has in some way deviated from that design. (See *Dierks v. Mitsubishi Motors Corp., supra*, 208 Cal.App.3d 352, 354-355: Focus is on whether the particular product involved in the incident was manufactured in conformity with the manufacturer's design; see also *Morson, supra*, 90 Cal.App.4th at p. 789.) Here, we are unable to separate out the raw material, NRL, from the forming and processing of it, nor does Plaintiff argue we should. The NRL gloves in this case were processed exactly as Baxter intended that they should be, in light of the state of its scientific and manufacturing knowledge at the time. This was true of all the various lines of production, even though testing was ongoing at some and not others at times. That later developments showed the product was subject to immense

improvement does not necessarily show the products processed earlier were defective, under either formulation of the *Barker* test. The fact that simultaneously manufactured gloves were subject to different standards at different production lines, due to the status of the manufacturer's research and development, where scientific knowledge was as inconclusive as is shown by this record, does not require that some items must be deemed defective under a manufacturing defect approach. Rather, such arguments actually deal with design defect evidence, and the jury properly did not receive those instructions in this case. Allowing the Plaintiff's verdict to stand here would be inconsistent with the applicable public policies as stated above, for lack of any supporting evidentiary showing.

In conclusion, we believe that Plaintiff's efforts are ineffective to show that the various NRL gloves that were manufactured precisely as intended, that complied with applicable governmental standards, and that fulfilled their primary barrier function, nevertheless have manufacturing defects due to the existence of evidence of the testing, improvement, research and development efforts, targets and goals of the manufacturer, at different times and locations, reflective of the state of scientific knowledge regarding latex protein levels of exposure available to the relevant participants in this health care product context. The products did not differ from the manufacturer's intended result, nor did they have materially significant differences among identical units from the same product line. (*Barker, supra,* 20 Cal.3d at p. 429.) The motion for JNOV was properly granted.

II

NEW TRIAL MOTION

As fully explained by the court in *Fountain Valley Chateau Blanc Homeowner's Assn. v. Department of Veterans Affairs* (1998) 67 Cal.App.4th 743, 751 (*Fountain Valley*), ordinarily, the function of a new trial motion is to allow a reexamination of an issue of fact, and accordingly, on review of a ruling on a new trial motion, the abuse of discretion standard will apply. (See, e.g, *Jones v. Evans* (1970) 4 Cal.App.3d 115, 121.) However, an appellate court has the power to look at the substance of a new trial ruling rather than just its title. (*Fountain Valley, supra,* 67 Cal.App.4th at pp. 750-753.) If the effect of the ruling is actually closer in nature to a directed verdict or a judgment notwithstanding the verdict, then in such a case, the ruling may be deemed to have been based upon a conclusion of law, and de novo review is appropriate. (See *id.* at pp. 750-753.)

In this case, the effect of the new trial ruling was to allow Baxter to prevail as a matter of law, since the relevant evidence had already been presented on the strict liability theories. Only the manufacturing defect theory was the basis of the rulings, as the court rejected the other grounds argued. We should treat the order as a legal ruling that overturned the jury verdict, and uphold the judgment that disposed of that verdict, if the record allows the issues to be decided as matters of law. (See, *Fountain Valley, supra,* 67 Cal.App.4th at pp. 750-753.) We believe that it does. Although the trial court granted the new trial motion in the alternative to the JNOV, we deem that grant to be an effort to dispose of the case for the same reasons outlined above as applied in the other

context. No new trial is appropriate on this record, as it demonstrates that the manufacturing defect theory cannot as a matter of law apply to the existing facts in the record. Nor has Plaintiff demonstrated any way in which different or new evidence could be presented to justify further efforts along those lines. We deem the new trial order to be moot in light of our analysis of the JNOV issues and our affirmance of the JNOV order.

III

DESIGN DEFECT THEORY BASED ON CONSUMER EXPECTATIONS

Finally, McGinnis seeks reversal of the judgment on the basis that the court erred in refusing to instruct the jury on a design defect theory based on a consumer expectations approach. She contends she was effectively nonsuited on that theory. As already alluded to, the prior opinion by this court in *Morson, supra*, 90 Cal.App.4th 775, 784-785, arising out of the general order made in this case that precluded plaintiffs in these coordinated cases in future trials from seeking such instructions, upheld that general order as a proper interpretation of *Barker, supra*, 20 Cal.3d 413.

McGinnis, however, seeks a different result on the grounds that although the trial court's order unquestionably applied to her case, and although that order had been upheld in writ proceedings as of the time of the briefing in this matter, it had not yet become final by the time the opening brief was filed. While that may be so, the *Morson* opinion is now final and we are entitled to regard it as correct and also as binding upon McGinnis.

McGinnis also asserts that Baxter raised heightened expectations of consumer safety by advertising its product as "The Right Choice," referring to its efforts to reduce

protein amounts in NRL gloves, and that this evidence produced at trial goes beyond the record that was considered in *Morson, supra,* 90 Cal.App.4th 775. We believe the analysis in *Morson* sufficiently covers this ground. Moreover, McGinnis has presented nothing in the record or in the applicable authorities to justify a different result. She did not present any alternative design defect theory under a risk-benefit analysis. (*Id.* at p. 785.) She accordingly failed to place directly before the jury any design defect theory that was not incorrectly based upon the consumer expectation test. In any case, as discussed above, her manufacturing defect evidence closely resembled the evidence she would have gathered for a design defect claim, and it does not support the verdict. We need not further consider this claim, as neither version of the design defect test will legitimately apply under these factual and procedural circumstances.

DISPOSITION

The judgment and order are affirmed. Each party to bear its own costs.

CERTIFIED FOR PUBLICATION

HUFFMAN, J.

WE CONCUR:

KREMER, P. J.

NARES, J.